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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,492	11/20/2003	Christopher C. Toly	SIMU0004	8227
25268 7590 04/19/2007 LAW OFFICES OF RONALD M ANDERSON 600 108TH AVE, NE SUITE 507 BELLEVUE, WA 98004			EXAMINER MUSSELMAN, TIMOTHY A	
			ART UNIT	PAPER NUMBER
			3714	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/718,492

Applicant(s)

TOLY, CHRISTOPHER C.

Examiner

Timothy Musselman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7-9,15,16,20-35,37-61 and 74-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7-9,15,16,20-35,37-61 and 74-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

In response to the amendment filed 6/6/2006, claims 1-3, 7-9, 15-16, 20-35, 37-61, and 74-87 are pending. Claims 4-6, 11-14, 17-19, and 36 have been withdrawn from consideration as a non-elected species subject to rejoinder upon allowance of a generic claim. Claims 42, 46, and 62-73 have been cancelled as being directed to a non-elected invention.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/695,380, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The parent case only discloses the tissue structures and fluid channels of a mannequin device for surgical training. There are no sensory, control, monitoring, or electrical elements of any kind. The disclosure of the parent application incorporates Younker (US 5,951,301) by reference. Although Younker discloses a surgical training device utilizing a tissue structure comprising a conductive elastomeric layer, said layer is *exclusively* to simulate the surgical process of electrocauterization. Younker does not disclose *any* evaluation, sensor, or control circuits with or without a conductive elastomeric layer. Claim 2 is supported by the parent application, and will be afforded the earlier filing

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date under 35 U.S.C. 120 of 10/23/2000. Claims 2-3, 7-9, 15-16, 20-35, 37-54, 56-61, and 74-87, fail to comply with the enablement requirement of 35 U.S.C. 112, 1st paragraph, with respect to the parent application, in at least so much as the parent application does not disclose an evaluation circuit, and claim 55 is unsupported in at least so much as the parent application does not disclose a conductive elastomeric layer *encapsulated* between two elastomeric layers, and thus these claims will be considered with respect to the filing date of the instant case of 11/20/2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[1] Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. It is unclear what applicant means by "...when at least a portion of the simulated physiological structure is touched...". It is unclear what manner of *touching* applicant is claiming (i.e. touched with a hand, medical instrument, etc). Claims 8-9 are rejected for their incorporation of the above.

Claim Rejections - 35 USC § 102

The following is a quotation of the relevant portions of 35 U.S.C. 102 that forms the basis for the rejections made in this section of the office action;

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Younker (US 5,951,301).

[2] Regarding claim 1, Younker discloses a physiological training and evaluation simulator suitable for training and testing personnel, comprising a simulated physiological structure and a circuit including a conductive elastomer. See col. 2: 23-37.

Claims 2-3, 7, 15-16, 20-25, 26-30, 31, 35, 37, 43-45, 47-50, 53-61, 74, and 77-78, are rejected under 35 U.S.C. 102(e) as being anticipated by Nicholls (US 2003/0068606).

[3] Regarding claims 2, 29-30, 45, 47, 55, 74, and 77, Nicholls discloses a physiological training and evaluation simulator suitable for training and testing personnel, comprising a simulated physiological structure. See paragraph 21. Nicholls further discloses an evaluation circuit configured to provide a signal relating to a simulated procedure being performed on the simulated physiological structure indicating a rate of learning. See paragraph 26. Nicholls further discloses wherein the structure comprises a plurality of fluid channels (claims 29-30). See paragraph 25, and note that the human arterial system is a fluid channel. Nicholls further teaches wherein the evaluation circuit includes a conductive elastomer to enhance the realism of the simulator. See paragraph 22. Nichols further teaches wherein said conductive elastomer comprises a first elastomeric layer, a second elastomeric layer, and a conductor encapsulated there between (claim 55). See paragraphs 13 and 14.

[4] Regarding claim 57, Nicholls discloses a method for making a medical training simulator suitable for medical skills training and evaluation, the method comprising the steps of determining a physiological structure that the medical training simulator is to simulate (skin, see paragraph 22) determining a

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simulated medical procedure that will be performed on a simulated physiological structure corresponding to the physiological structure (see paragraph 15), constructing a medical training simulator including a simulated physiological structure corresponding to the physiological structure of the first step. See paragraph 22. Nicholls further discloses an evaluation circuit comprising a conductive elastomer configured to provide feedback relating to the simulated medical procedure. See paragraph 14.

[5] Regarding claims 3, 7, 16, 48, 56, and 58-61, Nicholls further discloses wherein the evaluation circuit is configured to provide the signal when a specific portion of the simulated physiological structure is manipulated (touched, in proximity too...). See paragraph 11.

[6] Regarding claim 15, Nicholls discloses wherein the evaluation circuit is configured to provide the signal when a manipulation of at least a portion of the simulated physiological structure causes the evaluation circuit to open. See paragraph 14. Notice that the *removal* of the needle in this citation would result in an *opening* of the circuit, which provides a signal indicating that the needle has been removed (i.e. manipulated).

[7] Regarding claim 20, Nicholls further discloses wherein the simulator comprises additional conductive elastomer evaluation circuits configured to provide a signal when a different portion of the simulated physiological structure is manipulated during a procedure performed on the simulated physiological structure. See paragraph 14.

[8] Regarding claims 21-22, 49-50, Nicholls further discloses wherein the physiological training and evaluation simulator comprises an indicator (light source) coupled to the evaluation circuit, such that in response to the signal the indicator provides an indication relating to the performance of the simulated procedure. See paragraph 29.

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[9] Regarding claim 23, Nicholls further discloses wherein the indicator comprises a meter, a change in the meter providing feedback regarding the performance of the procedure. See paragraph 27. Note that the display is a meter in that it is interpreting sensed electrical signals and displaying data resulting therefrom.

[10] Regarding claims 24-25, Nicholls further discloses twherein the simulated physiological structure is a simulated human *tissue* structure, and wherein the simulated human tissue structure comprises at least one simulated membranous layer comprising at least one elastomeric layer; and at least one simulated sub-membranous layer comprising at least one elastomeric layer underlying a first membranous layer. See paragraphs 13 and 14.

[11] Regarding claims 26-28, Nicholls further discloses wherein the evaluation circuit is implemented as a three-dimensional grid encompassing the majority of the structure. See paragraph 14.

[12] Regarding claim 31, Nicholls further discloses wherein the evaluation circuit couples to a processor configured to manipulate the signal. See paragraph 29. Note that the signal is manipulated for display purposes.

[13] Regarding claim 34, Nicholls further discloses wherein the evaluation circuit is implemented with a plurality of branches that extend throughout at least a portion of the simulated physiological structure where the simulated procedure will be performed, so that by monitoring the plurality of branches, the processor determines a three-dimensional location of an instrument during the simulated procedure. See paragraph 14.

[14] Regarding claims 35 and 43-44, Nicholls further discloses wherein the simulated structure is a surgical trainer that is an organ (i.e. a grouping of tissues into a distinct structure). See paragraph 10.

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[15] Regarding claim 37, Nicholls further discloses a neural network that substantially corresponds to a neural network in a physiological structure upon which the simulated physiological structure is modeled. See paragraph 28.

[16] Regarding claims 53 and 54, Nicholls further discloses wherein the evaluation circuit comprises conductive portions separated by a non conductive portion, such that the proper execution of the simulated medical procedure requires the removal of the non conductive portion and the conductive portions to be coupled to complete the circuit. See paragraph 14. Note that the evaluation circuit in this citation includes the conductive layer *and* the probe. The insertion of probe into the simulated skin displaces (removes) the insulator as it is inserted into the simulated structure a certain distance (gap) to contact the conductive elastomer portion of the evaluation circuit, thus completing the circuit.

[17] Regarding claim 78, Nicholls further discloses wherein the indication produced by the conductive elastomer-based evaluation circuit is used to *determine* a physiological response for the medical training simulator to emulate. See paragraph 28.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Claims 8-9, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606), in view of D'Antonio et al. (US 5,589,639).

[18] Regarding claims 8-9, and 51-52, Nicholls discloses an evaluation circuit to determine the position and correctness of the simulated medical device relative to the simulated structure as described above, but fail to explicitly teach wherein the evaluation circuit comprises a capacitance sensitive switch, (claim 8), a resistance sensitive switch (claim 9), and wherein the simulated medical device includes an inductor wherein the evaluation circuit is configured to receive a current induced by the inductor when the simulated medical device is correctly utilized to perform the simulated medical procedure, (claim 51), and wherein the evaluation circuit comprises a capacitance based sensor (claim 52). However, D'Antonio teaches of a device for use in medical procedures that is directed towards solving the problem of sensing parameter changes in an environment and producing a corresponding signal. See col. 5: 21-27, wherein D'Antonio teaches of a Schmitt trigger switching device that is dependant upon a resistive, capacitive, or inductive signal from the respective sensors. D'Antonio further discloses an inductor to induce a signal to the sensing circuit. See col. 4: 45-50. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Nicholls to include the sensor and switch types of D'Antonio, so as to provide an effective manner in which to sense and transform the physical parameters of the simulation into electrical signals for processing and display.

Claims 30 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606) in view of Boscaro Gatti et al. (US 4,459,113).

[19] Regarding claims 30 and 76, Nicholls fails to teach wherein the evaluation circuit is incorporated into the wall of at least some of the fluid channels as described above with regard to claim 2, and further fails to teach wherein the evaluation circuit provides the signal if such a wall is damaged during the simulated procedure. Additionally, Nichols discloses visual indicators as described above with regard to claim 22,

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but fails to teach of an audio indicator. However, Boscaro Gatti discloses a surgical training device that teaches of all of these features. See col. 2: 39-61. It would have been obvious to one with ordinary skill in the art at the time of the invention to incorporate the audible excessive pressure indications of Boscaro Gatti into the system of Nicholls in order to create realistic alerts that indicate the student is performing the procedure in a manner that could injure a patient.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606) in view of Chosack et al. (US 6,857,878).

[20] Regarding claims 32-33, Nicholls discloses a physiological control element configured to produce a simulated physiological response in the simulated physiological structure including a pump. See paragraph 25. Nicholls fails to teach of the physiological control element being coupled to the evaluation circuit so that the processor uses the evaluation circuit to control the physiological control element, and wherein the control element includes a servo. However, Chosack teaches of a surgical simulation device that includes a responsive control element including a servo. See col. 3: 55-67. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the simulated physiological response mechanisms of Chosack, including the servo, into the simulation of Nicholls, so as to provide realistic simulated physiological responses that more closely mimic an actual surgical environment.

Claims 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606), in view of Strover et al. (US 5,967,790).

[21] Regarding claims 38-41, Nicholls discloses wherein the evaluation circuit is disposed proximate to a location on the simulated physiological structure at which a medical device will be employed in the simulated medical procedure, to evaluate whether a person performed the procedure properly (claims 39

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and 41). See paragraph 14. Nicholls fails to teach wherein the simulated physiological structure comprises a simulated joint or bone. However, Strover discloses a surgical training device that includes a knee joint and accompanying bone structure. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the joint and bone aspects of Strover into the simulation device of Nicholls, in order provide additional and diverse training opportunities for the user.

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606) in view of Pugh (US 6,857,878).

[22] Regarding claim 75, Nicholls fails to teach wherein the indication produced by the evaluation circuit is provided to another party, so that the person is unaware of the indication during the execution of the simulated medical procedure. However, Pugh teaches of this feature in col. 8: 25-35. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to incorporate this feature of Pugh into the system of Nicholls, in order to allow for complete procedures to be carried out before feedback is given so that a students skill can be accurately tested.

Claims 79-81, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606) in view of Beach et al. (US 6,857,878).

[23] Regarding claims 79-81, Nichols disclose a physiological training and evaluation simulator comprising a simulated physiological structure including a conductive elastomer-based evaluation circuit configured to provide data relating to a simulated procedure being performed on the simulated physiological structure and a controller coupled to the conductive elastomer-based evaluation circuit, the controller being configured to implement a plurality of functions. See the rejections of claims 2 and 31 above. Nicholls fails to teach of storing data obtained from the conductive elastomer-based evaluation circuit and processing the data obtained from the conductive elastomer-based evaluation circuit to

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determine a score rating a quality of the simulated procedure and storing said scores for later comparison to determine a rate of learning. However, Beach teaches of a surgical simulation device that includes these features. See col. 11: 66-67, and col. 12: 43-48. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the scoring aspects of Beach into the system of Nicholls, so as to allow users of the simulation to monitor their performance and improvements therein.

[24] Regarding claims 85-87, Nicholls further discloses wherein the simulated physiological structure is a human patient simulator including a plurality of simulated anatomical features, thereby enabling the human patient simulator to support the simulation of a plurality of different simulated procedures (claim 85). See paragraph 13. The system of Nichols includes all of the features of claims 86 and 87 as described above with regard to claims 26 and 27.

Claims 82-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls et al. (US 2003/0068606), Beach et al. (US 6,857,878), and in further view of Younker (US 5,951,301) and Chosack et al. (US 6,857,878).

[25] Regarding claims 82-84, Nicholls/Beach fail to teach of a physiological control element configured to produce a simulated physiological response in the simulated physiological structure, the physiological control element being coupled to the evaluation circuit so that the processor uses the evaluation circuit to control the physiological control element, and wherein the control element includes one of a pump and a servo (to provide a movement of at least a portion of the simulated structure). However, Nicholls teaches of a pump used to circulate fluid to increase the realism of the simulation (see paragraph 25), and Chosack teaches of a surgical simulation device that includes a responsive control element including a servo. See col. 3: 55-67. It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the simulated physiological response mechanisms of Chosack into the system of

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Nicholls/Beach, so as to provide realistic simulated physiological responses that more closely mimic an actual surgical environment.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection. This office action is made NON_FINAL.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy Musselman whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto, can be reached on (571)272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KATHLEEN MOSSER
PRIMARY EXAMINER